THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GEORGE CHANG
 and ROSALIND LUM

Appeal No. 1997-1770 Application 08/235,488

ON BRIEF

Before WINTERS, CAROFF and JOHN D. SMITH, <u>Administrative</u> <u>Patent Judges</u>.

CAROFF, Administrative Patent Judge.

DECISION ON APPEAL

This decision on appeal relates to the final rejection of claims 1-20, all of the pending claims in appellants' application.

The claims relate to a method for detecting coliform bacteria including $\underline{E.\ coli}$ (see claim 1), and an associated

detecting medium (see claim 17) which includes a §-D-galactosidase substrate and a carbohydrate metabolizable by a plurality of coliform species but not metabolizable by E. coli. Independent claims 1 and 17 are reproduced below as representative of appellants' invention.

- 1. A method for detecting coliform bacteria and \underline{E} . coli, said method comprising the steps of:
 - (a) contacting a bacterial colony with a §-D-qalactosidase substrate;
- (b) contacting said bacterial colony with a first carbon source metabolizable by a plurality of coliform species but not metabolizable by <u>E. coli</u>, wherein metabolism of said first carbon source provides a reaction product at said colony;
- (c) detecting a first reaction product signal of said $\underline{\mathbf{s}}$ -D-galactosidase substrate at said colony;
- (d) detecting a second reaction product signal of said carbon source at said colony; wherein the absence of both said first and second reaction product signals indicates the presence of non-coliform bacteria in said colony, the presence of said

first and absence of said second reaction product signal indicates the presence of \underline{E} . coli in said colony, and the presence of said first and

second reaction product signals indicates the presence of non- $\underline{\text{E. coli}}$ coliform bacteria in said colony.

- 17. A sterile medium for use in detecting coliform bacteria and $\underline{E.\ coli}$, said medium comprising:
 - (a) a \S -D-galactosidase substrate;
- (b) a carbohydrate metabolizable by a plurality of coliform species but not metabolize by $\underline{\mathtt{E.}}$ coli; and
 - (c) salts.

The following references of record are relied upon by the examiner as evidence of obviousness:

Edberg 4,925,789 May 15, 1990 Roth et al. (Roth) 5,210,022 May 11, 1993

"Dehydrated Culture Media and Reagents for Microbiology, in Difco Manual," 203-4 (10th ed., Detroit MI, DIFCO Labs, 1984).

Chang, G., "Tactics for Combining the Coliform and Indole Tests: Simple Media for Both Total Coliforms and <u>Escherichia Coli</u>," 53 Journal of Food Protection 910 (October 1990).

Chang, G., et al. (Chang), "Tryptophan and Galactoside (TAG) Media: Simple and Specific Ways to Enumerate E. coli and Total Coliforms in Water and Food," 90 Society of Microbiology, no. 0, 290, abstract Q-12 (1990).

Bainbridge, B. et al. (Bainbridge) "Improved methods for the detection of \$-galactosidase activity in colonies of <u>Escherichia Coli</u> using a new chromogenic substrate: VBzTM-gal (2-(2-(4-(\$-D-galactopyranosyloxy)-3-methoxyphenyl)-vinyl)-3-methylbenzothiazolium toluene-4-sulphonate 80 <u>FEMS</u> <u>Microbiology Letters</u>, 319-24 (1991).

Atlas, R. et al. (Atlas), "<u>Handbook of Microbiological Media</u>," 132, 178 (Boca Raton, FL, CRC Press, no date available).

Brenner, K. et al. (Brenner), "New Medium for the Simultaneous Detection of Total Coliforms and <u>Escherichia Coli</u> in Water," 59 <u>Applied and Environmental Microbiology</u>, no. 11, 3534-44 (Nov. 1993).

All of the claims on appeal stand rejected under 35 U.S.C.

§ 103 for obviousness.¹ The claims, and the references applied against those claims, are grouped as follows:

- 1. Claims 1-7, 9, 11-14, 17 and 19 (Edberg).
- 2. Claim 10 (Edberg in view of Bainbridge, Brenner or Roth).
- 3. Claims 15-16 (Edberg in view of either Chang reference).
- 4. Claims 8, 18 and 20 (Edberg in view of the Difco Manual or the Handbook of Microbiological Media).

Based upon the record before us, we agree with appellants that the examiner has failed to establish a <u>prima facie</u> case of obviousness. Accordingly, we shall not sustain any of the rejections at issue essentially for the reasons presented in

¹The examiner has indicated in an Advisory Action (Paper No. 10) that all previously applied rejections under 35 U.S.C. § 112 have been overcome by amendment of claims. Accordingly, there are no 35 U.S.C. § 112 rejections before us on appeal.

appellants' Brief and Reply Brief.

For emphasis, we note that the teachings of Edberg are crucial to each of the rejections before us. Accordingly, we focus our remarks upon the shortcomings of that reference.

None of the other references applied by the examiner in conjunction with Edberg cure deficiencies of the primary reference.

As indicated by appellants, a fair reading of the Edberg disclosure reveals a crucial difference between the teachings of Edberg and appellants' invention. Where the focus is on detection of <u>E. coli</u>, Edberg suggests using a substrate which is <u>metabolizable by E. coli</u>, e.g. a <u>\$</u>-glucuronidase substrate.

To the contrary, appellants employ a unique <u>combination</u> of a <u>\$\scritter{\sinter{\scritter{\scritter{\scritter{\scritter{\scritter{\scritter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinter{\sinte\</u>

§ 103 to use the two specific substrates of appellants' claims in tandem to detect coliform bacteria and E. coli. For the most part, Edberg teaches use of a single nutrient-indicator substrate which is only metabolized by, i.e., is selective for, a particular target microbe. It is true that Edberg (col. 9-10; claim 16) also contemplates detecting both total coliforms and E. coli simultaneously by using a combination of a \S -galactosidase substrate (for total coliforms) and a \S glucuronidase substrate (for $E.\ coli$). The examiner has not presented any cogent reason, nor are we aware of any, why one of ordinary skill in the art would have been motivated to modify this combination to arrive at appellants' invention by replacing the \S -glucuronidase substrate with a carbon source, e.g. adonitol, which is metabolizable by a plurality of coliform species but not by E. coli. Adonitol is mentioned by Edberg (col. 8, 1. 3-16) but only in connection with a method for detecting K. pneumoniae. We find no suggestion in Edberg to use adonitol in combination with any other substrate, let alone in combination with a galactosidase substrate in particular for detecting coliform bacteria and E. coli.

Conceptually, the differences between Edberg and appellants' invention are significant. Whereas Edberg relies solely upon positive test results to confirm the presence of a particular microbe, appellants' invention is capable of detecting the presence of <u>E. coli</u> by negative inference when, for instance, a negative result is obtained relative to the selective carbon source (<u>absence</u> of a "second reaction product signal") coupled with a positive result relative to the galactosidase substrate (presence of a "first reaction product signal"). In order to establish a <u>prima facie</u> case of obviousness, the examiner would have to reconcile these differences. He has failed to do so.

For the foregoing reasons, the decision by the examiner is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge))))
MARC L. CAROFF Administrative Patent Judge) BOARD OF PATENT)) APPEALS AND
) INTERFERENCES)
JOHN D. SMITH Administrative Patent Judge)

MLC:hh

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